The AAFP Patient Safety Reporting System: Development and Legal Issues Pertinent to Medical Error Tracking and Analysis

Robert L. Phillips, Susan M. Dovey, John S. Hickner, Deborah Graham, Michele Johnson

Abstract

The Institute of Medicine makes the case that patient safety data are a critical input for redesigning care processes in ways that will make health care safer. Mandatory and voluntary error-reporting systems are sources of such data. However, a chasm of legal and practical problems exists between the collection of error reports and responding to reporting providers to improve the quality and safety of the systems in which they work. Between 2000 and 2004, the American Academy of Family Physicians (AAFP) developed and tested a voluntary error-reporting system. In this paper we discuss the current design of the AAFP's system and the legal and practical constraints that stand in the way of its becoming a more robust quality-improvement tool. We explain decisions to make the reporting system Web-based (rather than paper-based), to be anonymous (rather than confidential), to not provide direct or specific feedback to reporters, and to make it capable of receiving reports of both "sentinel" events and "intensive" reporting. This paper will clarify what is currently done with error reports and how, despite current limitations, the reporting system informs and promotes a variety of other quality initiatives of the AAFP. We also highlight how this reporting system could more robustly improve patient safety and quality in health care if legislative and other remedies are implemented to bridge the existing chasm.

Introduction

In *To Err Is Human*, the Institute of Medicine (IOM) recognized that error-reporting systems had dual, but simultaneously difficult functions of increasing accountability and providing information that may lead to safer health care.[1] In IOM's estimation, mandatory reporting systems lend themselves to the former, and voluntary reporting systems to the latter. The IOM recommended funding and support of voluntary reporting efforts, specifically recognizing the need for confidentiality provisions, reporter feedback mechanisms, and improved understanding of how reported information is used. Leaders of the patient safety movement agree that voluntary reporting systems can measurably improve safety if reporting is protected against discovery and provides reporters with useful information from expert analysis.[2] They also suggest that the complexity and expense of running a national voluntary error-reporting system would be

Report Documentation Page

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
2005	**N/A**	**-**

4. TITLE AND SUBTITLE	5a. CONTRACT NUMBER
The AAFP Patient Safety Reporting System: Development and Legal Issue Pertinent to Medical Error Tracking and Analysis	5b. GRANT NUMBER
	5c. PROGRAM ELEMENT NUMBER
6. AUTHOR(S)	5d. PROJECT NUMBER
	5e. TASK NUMBER
	5f. WORK UNIT NUMBER
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) **Agency for Healthcare Research and Quality 540 Gaither Road, Suite 2000 Rockville, MD 20850**	8. PERFORMING ORGANIZATION REPORT NUMBER
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)	10. SPONSOR/MONITOR'S ACRONYM(S)
	11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION/AVAILABILITY STATEMENT
Approved for public release, distribution unlimited

13. SUPPLEMENTARY NOTES
Published in Advances in Patient Safety: From Research to Implementation. Volumes 1-4, AHRQ Publication Nos. 050021 (1-4). February 2005. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/qual/advances/

14. ABSTRACT

15. SUBJECT TERMS

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			
unclassified	**unclassified**	**unclassified**	**UU**	**14**	

overwhelming, and that specialty-based or system-specific reporting programs are more feasible.

Researchers at the Robert Graham Center, a research center and division of the American Academy of Family Physicians (AAFP), seized upon *To Err Is Human* and its recommendations for voluntary reporting. The Graham Center staff felt compelled to turn its research focus to patient safety, due to the scarcity of information about threats to patient safety in outpatient settings, where most Americans receive most health care.[3] It was decided that an early pilot study was needed to see what threats to patient safety family and general physicians would recognize and report, and whether it made a difference if they reported by a Web- or paper-based system. This initial study, launched in 2000, led to three subsequent studies within the AAFP National Network for Family Practice and Primary Care Research (National Network) and with collaborators in six other countries. These studies have helped refine a specialty-based, Web-enabled error-reporting tool and have demonstrated its utility for identifying threats to the safety of patients who enter the primary care system.[4] This paper is about this error-reporting tool—its evolution, the data it yields, reporters' experience with it, ways that it could contribute to other reporting programs, the legal and practical barriers to its full utilization, and the potential for its role in a broader patient safety agenda if barriers are lifted.

Background

Family practice is complex, characterized by customized care that responds to individual patients' needs, values, and preferences across a broad spectrum of health and illness concerns.[5–7] Its diversity, scope, and variation in structure and infrastructure may offer more opportunity for error than hospital-based care, which tends to be more highly regulated and procedure oriented. Making primary care safer for patients is complicated by a lack of understanding of the nature and distribution of errors that occur in this setting and that are amenable to systematic change. As well, many primary care physicians are only tenuously connected to other providers and may not be recognized as part of some health care delivery systems.[8] Malpractice data reveal that most error-related claims for primary care physicians come from care delivered outside of hospitals, and suggest that seemingly trivial errors can severely injure and kill people.[9]

Prior to our own research, only two studies had explored the epidemiology of errors in primary care. One, an Australian study, used incident reports to describe events that resulted, or could have resulted, in harm to patients.[10] These events were not necessarily errors. The other study reviewed a risk management database, applying a taxonomy developed from review of hospital records.[11] The growing body of evidence, and the IOM patient safety report series, revealed that the health system could cause substantial harm, alerting the U.S. public and politicians of the need to protect people from safety threats. Primary care providers, including family physicians, had so far largely been excused from engaging in discussions about medical errors. While many important initiatives in

hospitals offered hope for greater patient safety, other equally important opportunities were being overlooked because they existed outside of hospitals.

The AAFP error-reporting system: AAFP Patient Safety Reports

In developing the AAFP Patient Safety Reports, we attempted to design in the key characteristics of voluntary error-reporting systems proposed by safety experts to the degree possible.[2, 12] These key characteristics are that the reporting systems be nonpunitive and undiscoverable, confidential, timely and responsive, and easy to use. As recommended by the IOM, we designed a reporting system that could support causal analysis, including free-text descriptions of error events, guided by a standard set of questions.[13] Also in keeping with recommendations, we developed a core group of independent peer experts to analyze the error reports.

AAFP error-reporting research

The AAFP error-reporting system and the International Taxonomy of Medical Errors in Primary Care have been developed and revised based on four research studies carried out in family physicians' offices between 2000 and 2004.

Our first study, completed in January 2001, taught us that physicians recognized many errors and were willing to report them, even errors with serious adverse patient outcomes.[3] Fifty physicians of the AAFP National Research Network were randomly assigned to either arm of a crossover trial to test whether there were differences in reporting by paper or computer. This study was an early foray into describing the spectrum of errors recognized by physicians in primary care. The paper system included a pocket-sized paper card with prompts to report data items, and the computer reporting system had the same data prompts. Errors were defined as events in physicians' practices that should not have happened and were not anticipated. Physicians were encouraged to identify an incident "that should not happen in my practice and I don't want it to happen again." These could be administrative or clinical errors. They could be adverse events (events resulting in unintended harm) or near misses (events that had the potential to cause harm). The main outcome measures were error category, error rate, and error consequence.

Forty-two physicians reported 343 incidents over 10 weeks. Thirteen reports (4 percent) were of adverse events not arising from an error, 283 (83 percent) were of mistakes in care arising from system and process failures, and 47 (14 percent) were of errors in clinical judgment. Further breakdown of these errors is given in Table 1. Based on data from paper reports only, the error-report rate in this study was 45 per doctor per year, or about 1 error per working week. There was no clinical or cost consequence in 54 percent of the error reports. Appropriate care was delayed or extended in 22 percent of reports, and additional financial costs were reported in 18 percent. Nine of the reported errors

Table 1. Distribution of error types from three AAFP error-report studies

Error types	AAFP 1st study (n = 330) % error reports	International (n = 429) % error reports	AAFP 2nd study* (n = 838) % error codes
Process errors	86	79	96
Office administration	31	19	51
Filing system	12		9
Chart complete/available	8		19
Patient flow	2		6
Message handling	4		3
Appointments	3		12
Investigations	25	17	13
Treatments	23	26	16
Medications	17		14
Communications	6	14	13
Payment	1	1	3
Workforce management		2	1
Knowledge and skills	14	21	4

*More than one error could be coded for each report in this study.

precipitated hospital admission, and one resulted in death. No judgment about the severity of these consequences was sought from reporters or constructed by the research team in this initial study. It seems reasonable to suppose that a death—the result of a mishandled phone message—was the most severe outcome.

Legal and practical issues in preliminary studies

There were few legal precedents regarding discoverability of physician error reports in 1999. We chose to use ethical review and approval by an institutional review committee as the standard for protecting participating physicians. In the research design, we used many safeguards to protect the identity of the reporting physicians. We destroyed any documentation that could link error reports to individual physician reporters. Documents naming physician participants were meticulously shredded and computer files destroyed, leaving only data related to the reported error. These protections made it impossible to do root-cause analysis or to provide individualized feedback. Individual reports were never made publicly available, and publications from this study include only aggregate analyses of reports.[3, 13] On occasion, for training purposes, example cases combining the characteristics of two or more reports were discussed outside of the research team. Despite efforts to guarantee anonymity of the reporting physicians, however, some participants in this study are identifiable. Before publishing the paper reporting the study results, we asked participants if they wished to be named in the "Acknowledgments" section of the paper, and many elected to be named—choosing to make their participation in studying patient safety a matter of public record.

International research

The first AAFP study led to a Commonwealth Fund-supported study of errors reported by physicians in seven countries: the United States, Canada, New Zealand, England, the Netherlands, Australia, and Germany.[14] The computerized error-reporting system was tweaked to improve its function and no paper reports were made, because the first study provided reassurance that the types of errors reported by paper and computer would probably be similar. Reports remained anonymous because discoverability was not protected in every country.

This study involved more than 100 family and general physicians in the 7 countries, and they collectively reported more than 600 errors over a 12-week period in 2001. The distribution of error types was similar to the previous U.S. study. However, there were some differences associated with countries with greater computerization of practice (New Zealand, England). Most of the reports were related to process problems (79 percent), including treatments errors (26 percent), mistakes in office administration (19 percent), and communication problems (14 percent) (Table 1).

This Primary Care International Study of Medical Errors (PCISME) spawned the LINNAEUS (Learning in an International Network About Errors and Understanding Safety) Collaboration, which continues to work together and its members have become recognized patient safety research experts in their own countries.[15] With the PCISME study, the computerized error-reporting system was tested around the world in English and German and yielded important information about medical errors in primary care.[14]

Legal and practical issues raised by international research

This study raised new legal and practical issues. Data were reported in an electronic system developed in conjunction with a British software developer, who leased server space from a British Government agency for the central data repository. During report processing, however, the physical server holding study data at any particular time could be in any of a number of locations throughout the world. It was not the data themselves, but *access* to the data that was at issue. This is an important issue that may deserve further consideration by experts in international law: What access might third parties (such as malpractice lawyers) have to error report data that are not held in their own country—including data from reporters in other countries, operating under different legal codes? Some of the countries involved in our study have bilateral national agreements, but others do not. There is a body of legal precedent, for example, of American legal codes failing to have effect in New Zealand. And what is to be done about accessing data that have no known country of "residence" but exist only "virtually," as electronic data might? International studies and even international error-reporting systems are likely to be characterized by a unique set of legal issues that have so far not been addressed. Currently, most efforts are aimed at establishing legal frameworks for reporting systems *within* nations, and not *among* them.

Focused domestic research

After the first two studies, the AAFP received support for a Developmental Center of Excellence for Research in Patient Safety (DCERPS) from the Agency for Healthcare Research and Quality (AHRQ) (Grant Number 5 P20 HSO1 1584) and a supplemental patient safety research grant (AHRQ Grant Number 5 R21 HSO 13554). These grants were an important next step for AAFP's patient safety agenda and competencies. Among other things, they permitted formalization of the error-reporting system as an in-house, Web-based process.

In 2003, the DCERPS launched two error-reporting studies in the National Network to address questions raised in the first two studies. We hypothesized that physicians might identify different errors than their staff and patients. Family physicians, their staffs, and their patients from 10 clinics across the United States were asked to submit error reports continuously during a 10-week period, including 5 intensive reporting days during which they were to report every error they witnessed rather than just those they thought were important to report, using the same error definition. Physicians and staffs were given the option of reporting via the Internet to the AAFP Patient Safety Reports secure Web site or via written reports. Patients had the same options and also an automated telephone reporting system. The participants submitted 838 reports (Table 1). The overwhelming majority of reports were made by the Web-based system for all reporting groups.

Legal and practical issues raised by DCERPS research

Federal funding carries legal protections from discoverability. However, because these legal protections had never been tested, we maintained the anonymity of reporters. We did so over protests from our reporting physicians, who would have preferred receiving specific feedback. We assured anonymity by using reporter codes specific only to reporter types, not individuals, and by removing "cookies" and other report evidence from reporters' computers with each submission. To enhance data security and the protection of reporters, the AAFP invested in more robust firewalls within the error-report server, and separated report data from the reporting process server the moment reports were submitted. The AAFP funded a formal, external test of the system's security before implementing the studies.

Summary of quantitative findings from error-reporting studies

Table 1 summarizes the distribution of the types of errors in the preliminary AAFP study, the international study, and the DCERPS study—the three primary care patient safety studies described above. Process errors (83 percent, 79 percent, and 96 percent, respectively) surpassed knowledge and skill errors (14 percent, 21 percent, and 4 percent, respectively) in all three studies. The most commonly reported health process errors in all three studies were office administration errors (31 percent, 19 percent, and 51 percent, respectively) and treatment errors

(23 percent, 26 percent, and 16 percent, respectively). Investigation errors (25 percent, 17 percent, and 13 percent, respectively) were also common.

Several of the most severe outcomes resulted from seemingly innocuous and common communication errors. Most notable, the mishandling of messages from patients was associated with two deaths and a fetal demise.*

Differences in study design and analysis may explain some of the differences between studies. Errors in the first two studies were reported only by physicians, but errors in the third study were reported by physicians, staffs, and patients. (Table 1 includes physician and staff data only.) In addition, the coding procedures used in the second U.S. AAFP study (the DCERPS study) differed slightly from those used in the first two studies. In the first AAFP study and in the international study, only one error code was assigned to each error report. If more than one error was reported, only the code corresponding to the first error was assigned to the report. The first two studies taught us that understanding how errors cascade was important. As a result, in the second U.S. AAFP study, all errors were coded. In addition, some errors could be assigned more than one code (e.g., an error could be assigned both an investigation error code and a communication error code). Consequently, the percentages included in Table 1 for columns two and three reflect the percent of error reports, while the percentages for column four reflect the percent of error codes.

Qualitative findings from AAFP error-report studies

The supplemental AHRQ grant to the DCERPS supported a study of testing processes (laboratory, radiology) that included incident reporting, as well as focus groups and human systems engineering clinic evaluations. The study focus included all steps involved in ordering, receiving, and responding to patient investigations. The aim was to describe testing process errors recognized by family physicians and their office staffs, to investigate causes and consequences of these errors, and to generate hypotheses about interventions that might avert testing process errors. Eight practices were to report these errors over a 48-week period in 2003. This was to be followed by qualitative focus groups in each practice, and human systems engineer evaluations in two of the practices.

Participants submitted 661 testing process errors, but the study ended early, in week 32, because reporting significantly tapered off. The error reports have not yet been coded and analyzed.

Focus groups conducted as part of this research revealed that participants found it easy to make reports, usually taking only 1–3 minutes. Major barriers to

* Two patients committed suicide after calling to say they were very depressed and considering suicide; both times their messages were not directly delivered to the physicians but simply placed on the doctors' desks, where they were found too late. The fetal demise occurred when a term-pregnant patient who called about not feeling her baby move was not appropriately triaged by a junior nurse covering the phones over lunch, and the message of the patient's phone call was placed in a stack of charts. The patient then sought help at an urgent care center, where she was forced to wait, only to be referred back to her own physician without evaluation. By the time the patient finally reached her physician's office, it was closed. She went to the emergency room, where she received the tragic news.

reporting were remembering to report and other time commitments, such as paperwork and clinical responsibilities. Many of the focus group participants reported that participating in the study led to increased group awareness of safety. While participants identified the need for major system changes—typically electronic health records, more staff, and staff training—they also felt that reporting led to more immediate beneficial changes than paper-based tracking systems. The latter included increased awareness of errors and increased diligence. One participant commented, "The study has made me painfully aware of the fact that we don't have a system and secondly, how difficult it is to set up a system." Many of the practices described practicewide changes they made, both small and large, as a result of participating in the study. One practice described how it changed from "writing everything down on little pieces of paper and sticking them on charts, to e-mailing back and forth on lab results."

Refining the Web-based reporting system

These studies have produced a Web-based error-reporting tool that contributes to our understanding of threats to patient safety in primary care. It is not the only method we have employed for this purpose, but it remains an important and evolving part of the AAFP patient safety research program. Future versions of the reporting system will emphasize data collected by pulldown menus and checked boxes, but some continued free-text component is essential.

The latter two DCERPS studies have developed the error-coding capacity of the research team and made it clear that timely analysis will require some level of automation, which is another essential focus of research. Our coding of report data has most recently turned from granularity—that is, using reports to finitely describe the taxonomy of errors—to functional aggregations of error types and causes. The goal is a taxonomy that can guide interventions and make sense of the cascades of errors that produce adverse outcomes and near misses. We are also leading an international conference on primary care patient safety taxonomies to better understand their functional differences, the knowledge they produce, and how they may be cross-walked to each other and to higher-level classifications. Revision of our primary care error taxonomy will likely lead to reporting-tool modifications. For a variety of reasons explained in the next section, the Web-based reporting tool will remain a research tool. Our next studies will focus on expanding the Web-based process to add a feedback function for reporters and embedding these in a Web-based quality-improvement collaborative.

Legal and practical barriers to voluntary reporting

Legal barriers

In Table 2, we have summarized some of the legal barriers and concerns noted during our studies, as well as the characteristics that safety experts believe to be necessary for a successful voluntary reporting system.[2] A major impediment to achieving a health system version of the Aviation Safety Reporting System

Table 2. Reporting system characteristics, barriers, results, and potential future

Reporting system characteristics	Barriers	Results	Future
Nonpunitive and undiscoverable	• Lack of legal protections from discoverability	• Reports are anonymous • Not able to share reports with other systems • Lack of trust by reporters • Limited reporting	• No/limited discoverability
Confidential	• Reporter and data security limitations	• Complicated measures to protect data and reporters	• Ongoing concern for data • Tested methods that protect reporters from identification • Ability to contact reporters to clarify reports
Independent report collection and analysis by peer experts	• No governmental option obvious • Lack of legislated designations for specialty organizations	• Focus difficult to break out of hospitals/health systems • Lack of trust by reporters • Gathering report data without analyses or safety/quality learning	• Trusted experts receive and analyze reports from all settings • Report analysis process embedded or closely linked to intervention, education, and communication mechanisms
Timely and responsive	• Lack of legal protections from discoverability • AAFP team currently small and analytic process tedious • Lack of national or international consensus on analytic process or classifications • Research juvenile regarding how to respond	• Reporters receive no direct or specific feedback • No way to contact reporters for more information on events • No ability to share relevant reports with other systems • Limited learning from report data • Limited opportunities to test interventions	• Reporters receive timely feedback about specific events, targeted tools for improvement, expert consultation, peer comparison reports, certification or licensure credits • Analytic processes are fairly automated • Research teams focused on learning from reporting system, doing intervention studies • Learning collaboratives common
Ease of reporting	• Independent, redundant reporting systems developing • Not embedded in care processes	• Burden placed on reporters to report multiple places, different formats • Reporter fatigue	• Reports are automatically shared between systems, across borders • Reports automatically generated and embedded in care process

(ASRS) is the lack of legislation making such a system confidential and nonpunitive. Such legislation need not preempt State or Federal laws that require reporting of adverse or sentinel health care events that result in serious harm or death. These protections need not limit or affect the availability of error-related information or evidence currently available from other sources, such as medical records. Legal protections for voluntary reporting systems could complement the Health Insurance Portability and Accountability Act of 1996 and State and Federal peer review laws, striking a balance between improving patient safety and ensuring accountability. This balance would achieve the IOM's aims.

The AAFP has joined more than 94 other medical organizations in supporting patient safety legislation that would establish federally certified patient safety organizations (PSOs). PSOs would be able to receive error reports confidentially, protected against discovery and subpoena, and share information with other certified entities,[16, 17] as described in Table 3. Disappointingly, in each of the past 3 years, Federal patient safety legislation offering legal protections has failed to become law. Operating under AHRQ-funded research protocols offers limited protections from discovery (so far, untested in court) and will potentially permit the AAFP to move beyond anonymous reports. However, these protections do not permit the error-reporting tool to be used outside of research protocols to improve patient safety. Lack of protective legislation stymies efforts to translate our research into practice.

The AAFP has invested significant time and resources in obtaining expert advice about the limitations of Federal protections, about other discoverability risks, and in maintaining state-of-the-art data protection. However, the AAFP cannot expose family physicians and their offices to the risks of nonanonymous error reporting until Federal protections are in place. The IOM recognized the tension between the public's demand for transparency and the health system's insistence on confidentiality and legal protection for reported errors.[13] The IOM came down on the side of protecting reports out of concern that discoverability and fear of retaliation would be major impediments to effective reporting. It called for enhanced protection in order to establish voluntary reporting systems and the development of a national patient safety database of de-identified data. It considered this protection essential for the integrity and effectiveness of patient safety learning systems.

Practical barriers

Even if Federal legislation clears these hurdles, the practical barriers to a national reporting system could be enormous. Leape estimates that such a system could attract reports of 0.5 to 5 million near misses annually.[2] This would be 15 to 50 times the number of reports to the ASRS; and if per-case report review costs approach that of the ASRS (about $70 per case in 2002), the total cost would be staggering. The United States has a few national reporting systems that are limited in their scope,[18] and Australia, England, and the Canadian province of Saskatchewan have or have announced plans to introduce national or provincial error reporting systems.[19, 20] If the legal and practical barriers to national

Table 3. General principles for patient safety reporting systems

1.	**Creating an environment for safety.** There should be a nonpunitive culture for reporting health care errors that focuses on preventing and correcting systems failures and not on individual or organization culpability.
2.	**Data analysis.** Information submitted to reporting systems must be comprehensively analyzed to identify actions that would minimize the risk that reported events recur.
3.	**Confidentiality.** Confidentiality protections for patients, health care professionals, and health care organizations are essential to the ability of any reporting system to learn about errors and effect their reduction.
4.	**Information sharing.** Reporting systems should facilitate the sharing of patient safety information among health care organizations and foster confidential collaboration with other health care reporting systems.
5.	**Legal status of reporting system information.** The absence of Federal protection for information submitted to patient safety reporting systems discourages the use of such systems, which reduces the opportunity to identify trends and implement corrective measures. Information developed in connection with reporting systems should be privileged for purposes of Federal and State judicial proceedings in civil matters, and for purposes of Federal and State administrative proceedings, including discovery, subpoenas, testimony, or any other form of disclosure. **(a) Scope.** The privilege for the information prepared for a reporting system should extend to any data, report, memorandum, analysis, statement, or other communication developed for the purposes of the system. This privilege should not interfere with the disclosure of information that is otherwise available, including the right of individuals to access their own medical records. **(b) No waiver.** The submission of health care error information to a reporting system, or the sharing of information by health care organizations or reporting systems with third parties in accordance with these principles, should not be construed as waiving this privilege or any other privilege under Federal or State law that exists with respect to the information. **(c) Freedom of Information Act.** Health care error information received by and from reporting systems should be exempt from the Freedom of Information Act and similar State laws. Such an exemption is necessary to preserve the privilege discussed in this principle. **(d) Impact on State law.** A Federal law is necessary to assure protection of information submitted to national reporting systems, but the Federal protection should not preempt State evidentiary laws that provide greater protection than Federal law. Providing such information to reporting systems should not constitute a waiver of any State law privilege.

voluntary error-reporting systems in the United States prove insurmountable, system-specific or specialty-based reporting systems are potential solutions.[2] These could feed information into a national database.

The AAFP has identified some other practical barriers to sponsoring a national patient safety reporting system. Our team has become adept and increasingly reliable in its coding of reports, but coding remains sufficiently tedious that opening the Web-based reporting system to the general membership of the AAFP would be impossible while using the current manual coding mechanisms. Most coding to date has focused on the primary error being reported. But some of the work done by us and others suggests that more attention to cascades of errors and the most proximal of identifiable errors may be more important for identifying potential remedies.[21, 22] Cascade and root-cause analyses will require considerably more time, a bigger coding team, and the ability to

query reporters. Our desire, shared by many of our study participants, is to have a feedback mechanism that offers evidence-based solutions to commonly reported errors.

A final practical issue for the near future is the need for specialized expertise in the storage and retrieval of large datasets.[23] Medicine has appropriately reached outside of itself to draw on the skills of human systems engineers and aviation safety experts to improve reporting systems and how we respond to the errors they identify. As future users of primary care medical error-reporting data seek to mine them for patterns, or to analyze them with data from other settings or systems, complex data must be organized to be easily retrievable. Expertise in data management and organization may reduce these hurdles for the future, and may actually ensure that reports to one system (or specialty) can flow to other databases appropriately.[23]

The future

With the lifting of legal hurdles and, perhaps, with the implementation of authorizing legislation, the AAFP could be designated a patient safety organization—the entity to which participating practices routinely submit error reports. Within such a PSO, voluntary error reporting could become an essential component for safety and quality improvement in health care (Table 2). The goal would be to build reporting and feedback systems with automated coding driven by a functional error-classification scheme that guides an evidence-driven feedback mechanism. This system would also give reporters access to the past experiences of other reporters and robust evidence about implementing systems that improve care.

Nearly 75 percent of family physicians belong to the AAFP and look to it as a trusted entity for improving the quality of the care they provide. Our studies suggest that members would make error reports to the AAFP, and when they did, they would want specific feedback to improve their performance. The AAFP could link reports and their analyses to a wider array of its existing programs to improve quality and safety. As a formal PSO, the AAFP could analyze reports, provide feedback to reporting practices, and provide tools for preventing similar errors, allowing participating practices to monitor their progress relative to peer-practices and to share relevant reports with other safety organizations. The AAFP could tailor its existing educational arm to reflect report findings, produce quality improvement publications and "toolboxes," e-mail "patient safety cases of the week" to its membership, and provide learning collaboratives. Physician participation would be linked to professional development, licensing requirements, and maintenance of certification. The AAFP's investments and vision expose a desire to combine its trusted relationship with members, its well-established educational infrastructure, and its new capacities to position itself as a catalyst for improving quality in primary care. Other medical professional organizations could similarly support their members.

The AAFP error-reporting system would become a part of routine research and learning. If the legal and practical barriers can be overcome, the AAFP could

join Federal and specialty partners, health systems, and other countries in doing patient safety research. The international LINNAEUS collaboration and the AAFP's leadership in exploring how its error taxonomy links to other patient safety classifications hint at this future. Outside of research, sharing report data across systems and borders could facilitate more robust learning. Medication error reports from primary care, for example, could be repackaged and shared with the Food and Drug Administration and other medication error-reporting processes.

Conclusion

Over the past 5 years, the American Academy of Family Physicians has developed and tested a Web-based, voluntary error-reporting system through a series of domestic and international studies. This research effort has produced an error-reporting process that is accepted and used by physicians and clinic staff. The reporting system feeds into a robust classification process that is revealing where things go wrong in primary care, how errors differ from inpatient settings, and potential ways to make care safer. Patient safety data are a critical input to the efforts of providers to redesign care processes in ways that will make health care safer for all patients.[1]

Our qualitative data reveal that participation in reporting errors can induce physicians and their staffs to modify error-prone systems in their practices. Currently, a chasm of legal and practical problems exists between the collection of error reports and providing constructive feedback to reporting providers to assist them in improving the quality and safety of their offices. These gaps require more study. Our research will move from anonymous reports to confidential reports under the legal protections afforded by Federal grant funding, so that we may begin testing direct feedback to reporters, doing root-cause analysis, and engaging the other education and dissemination programs of the AAFP. Whether this Web-based error-reporting system evolves beyond research, and whether the AAFP becomes a full-fledged change agent for primary care practice, depends on bridging the legal and practical chasms identified by the IOM and others.

Acknowledgments

We sincerely appreciate the help of Tom Robinett, J.D., general counsel of the American Academy of Family Physicians, for his help with the legal issues around discovery; and the considerable assistance of Lisa Klein in preparing this document.

Disclaimer: The information and opinions contained in research from the Robert Graham Center do not necessarily reflect the views or policy of the American Academy of Family Physicians.

Author affiliations

Robert Graham Center: Policy Studies in Family Medicine and Primary Care, Washington, DC (RLP). American Academy of Family Physicians (DG, MJ). University of Otago, New Zealand (SMD). University of Chicago (JH).

Address correspondence to: Robert L. Phillips, Jr., M.D., M.S.P.H., The Robert Graham Center, 1350 Connecticut Avenue, NW, Suite 201, Washington, DC 20036; phone: 202-331-3361; fax: 202-331-3374; e-mail: bphillips@aafp.org.

References

1. Kohn LT, Corrigan JM, Donaldson MS, editors. To err is human: building a safer health system. A report of the Committee on Quality of Health Care in America, Institute of Medicine. Washington, DC: National Academy Press; 2000.
2. Leape LL. Reporting of adverse events. NEJM 2002;347:1633–8.
3. Green L, Fryer G, Yawn B, et al. The ecology of medical care revisited. N Engl J Med 2001;344:2021–5.
4. Dovey S, Meyers D, Phillips R, et al. A taxonomy of medical errors in family practice. Qual Saf Health Care 2002;11:233–8.
5. Heath I, Evans P, van Weel C. The specialist of the discipline of general practice. BMJ 2000;320:326–7.
6. Donaldson M, Yordy K, Lohr K, et al. Primary care: America's health in a new era. Washington, DC: Institute of Medicine; 1996.
7. Olesen F, Dickinson J, Hjortdahl P. General practice—time for a new definition. BMJ 2000;320:354–7.
8. Institute of Medicine. Crossing the quality chasm: a new health system for the 21st century. Washington, DC: National Academy Press; 2001.
9. Phillips RL Jr, Bartholomew LA, Dovey S, et al. Learning from malpractice claims about negligent, adverse events in primary care in the United States. Qual Saf Health Care 2004;13:121–6.
10. Bhasale A, Miller GC, Reid S, et al. Analysing potential harm in Australian general practice: an incident-monitoring study. Med J Aust 1998;169:73–6.
11. Fischer G, Fetters M, Munro A, et al. Adverse events in primary care identified from a risk-management database. J Fam Pract 1997;45:38–9.
12. Cohen MR. Why error reporting systems should be voluntary: they provide better information for reducing errors. BMJ 2000;320:728–9.
13. Aspden P, Corrigan JM, Wolcott J, et al, editors. Patient safety: achieving a new standard for care. Committee on Data Standards for Patient Safety, Institute of Medicine. Washington, DC: National Academy Press; 2004.
14. Makeham MAB, Dovey SM, County M, et al. An international taxonomy for errors in general practice: a pilot study. Med J Aust 2002;177:68–72.
15. Sanders J, Esmail A. The frequency and nature of medical error in primary care: understanding the diversity across studies. Fam Pract 2003;20:231–6.
16. Brodie, JM. AAFP leaders make Capitol Hill pitch for patient safety reporting systems. FPReport; 2003. Available at: http://www.aafp.org/fpr/20030400/10.html.
17. Letter to the Senate in support of S. 720, Patient Safety and Quality Improvement Act; 2004. www.aafp.org. 2004. (Accessed 2004 Apr 19.)
18. Woolf A, Litovitz T. Reporting of adverse events (correspondence). NEJM 2003;348:1410–1.
19. Ehman A. Saskatchewan first with mandatory reporting of medical errors. CMAJ 2004;168:471.
20. Katikireddi V. National reporting system for medical errors is launched. BMJ 2004;328:481.
21. Reason J. Human error: models and management. BMJ 2000;320:768–70.
22. Dovey S, Fryer GE, Green L, et al. Toxic cascades. A comprehensive way to think about medical errors. Am Fam Physician 2001;63:847.
23. Johnson CW. What will we do with the data? Issues in the reporting of adverse healthcare events. Department of Computing Science, University of Glasgow, Glasgow, Scotland; 2004. Available at: http://www.dcs.gla.ac.uk/publications/PAPERS/7800/qhc.pdf.